OCT 12 2007

510(k) Summary

Submitter
SHINA CORPORATION
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Republic of Korea
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Date Prepared
July 11, 2007

Name of Device

Common Name:	Disposable blood collection needles
Proprietary Name:	VACU-MED® Blood Collection Needles (available in 20G, 21G, and 22G by 1" and 1½" lengths)
Classification Name:	Hypodermic single lumen needles
Regulation:	880.5570
Class:	Class II
Product Code:	FMI

Predicate Devices
The VACU-MED® Blood Collection Needles are substantially equivalent in intended use, function and basic composition to the currently marketed Greiner VACUETTE® (available in 20G, 21G, and 22G by 1" and 1½" lengths), K973620.

Device Description
VACU-MED® Blood Collection Needles are manufactured from tubular stainless steel sharpened at both ends that is attached to the hub. The hub is threaded on one side to connect with the needle holder which is used to guide the needle into an evacuated blood collection tube. This end of the needle is the shorter end and is fitted with a protective rubber sleeve and a hard plastic needle cap. The opposite end of the needle is 1" or 1½" for withdrawing blood and is fitted with a color coded hard plastic needle cap. The two needle caps protect the needle and maintain the sterility. The seal between the two needle caps is covered with a perforated paper label that simplifies identification and acts as a seal of integrity.

VACU-MED® Blood Collection Needles are a sterile single-use disposable product. The needles are non-toxic and non-pyrogenic, and are available in a variety of combinations of needle sizes (20 to 22 gauge) and needle lengths (1" and 1½").

Intended Use
VACU-MED® Blood Collection Needles are designed for use in venous blood collection.

Technological Characteristics
The VACU-MED® Blood Collection Needles have similar technological characteristics to the currently marketed predicate devices listed above. The VACU-MED® Blood Collection Needles are made from the same materials (stainless steel needle tubing, polypropylene hub and needle caps, rubber needle sleeve) as the Greiner VACUETTE® blood collection needles. The VACU-MED® Blood Collection Needles meet the following device specific standards:

ISO 7864 (1993), Sterile Hypodermic Needles for Single Use
ISO 7886-1 (1993), Sterile Hypodermic Syringes for Single Use
ISO 9626 (1991), Stainless Steel Needle Tubing for Manufacture of Medical Devices
ISO 6009 (1992), Hypodermic Needles for Single Use - Colour Coding for Identification

Performance Data (non-clinical or clinical)
The VACU-MED® Blood Collection Needles are substantially equivalent to the predicate devices based on the descriptive data, compliance with standards, and indications for use.

Conclusion
The technological characteristics and performance data for the VACU-MED® Blood Collection Needles demonstrates they are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Shina Corporation
Ms. Carole Stamp
Senior Principal Regulatory and Quality Advisor
Regulatory and Clinical Research Institute, Incorporation
5353 Wayzata Boulevard, Suite 305
Minneapolis, Minnesota 55416

Re: K071947
Trade/Device Name: Shina Corporation VACU-MED® Blood Collection Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen needle
Regulatory Class: II
Product Code: FMI
Dated: July 11, 2007
Received: July 31, 2007

Dear Ms. Stamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: Not assigned K071947

Device Name: Shina Corporation VACU-MED® Blood Collection Needles

Indications For Use:

VACU-MED® Blood Collection Needles are designed for use in venous blood collection.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071947